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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Qainton Van Rooven

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HAHN AND MOODLEY, LLP

548 Market Street

San Francisco, CA 94104

EXAMINER

KENNEDY, NICOLETTA

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

07/02/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/581,827	<b>Applicant(s)</b> ROOVEN ET AL.	
	<b>Examiner</b> Nicoletta Kennedy	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1 and 4-11 are currently pending.

### ***Priority***

This application, filed June 2, 2006, is a national state entry of PCT/IB04/52616, filed December 1, 2004, and claims foreign priority to South African application 2003/9481, filed on December 5, 2003. Applicants have provided a certified copy of the South African application. The instant claims are supported by the South African application.

### ***Withdrawn Objection and Claim Rejections***

1. The objection to the Specification is withdrawn in view of Applicant's amendment to the specification.
2. The rejection of claims 1, 4-5, 7 and 10 under 35 U.S.C. 102(b) as being anticipated by Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) is withdrawn in view of Applicants' amendments.
3. The rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) in view of Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999) is withdrawn in view of Applicant's amendments.

### ***New Claim Rejections Necessitated by Amendment***

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**4. Claims 1, 5, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14, 1995) in view of Visser et al. (WO 98/56325) (pub. Dec. 17, 1998).**

Independent claim 1 claims a transdermal patch with several features:

- (a) a selected irritating substance;
- (b) a layered construct adapted to be adhered to the skin;

(c) a defining depot cavity between a proximal and distal layer wherein the proximal layer is in contact with skin and is partially permeable and the distal layer is the outer layer and is impervious to the skin;

(d) a proximal layer that is less permeable to the substance than the skin and is made of elastomeric silicone; and

(e) a composite distal layer comprised of a first layer which is partially permeable to the irritating substance and is comprised of elastomeric silicone material and a second layer which is impervious to the irritating substance.

Regarding claims 1 and 6, Ebert et al. teach a transdermal delivery device comprising an impermeable backing material laminated to an adhesive layer (abstract and figure). The device further comprises a gelled drug layer between the distal adhesive layer and the proximal adhesive layer (abstract and figure). The adhesive layers are laminated together (p. 6). The backing material may be a silicone elastomer (p. 15). The distal and proximal adhesive layers may be the same and the distal and proximal layers may each be composite layers (p. 17). The distal and proximal layers may be semi-permeable to the drug and the thickness may be adjusted, for example to have quick release from the proximal layer and sustained release from the proximal layer (p. 17). Suitable adhesives include polysiloxanes (p. 16). However, Ebert et al. do not teach that the active agent to be delivered is dimethylformamide (DMF). Visser et al. cure this deficiency.

Visser et al. teach the transdermal administration of dimethylformamide (DMF), a polar compound, to treat a viral or microbial infection (p. 1).

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It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Ebert et al. with those of Visser et al. to use the transdermal delivery device of Ebert et al. to deliver DMF. One would have been motivated to do so because Ebert et al. teach that the term “drug” or “pharmacologically active agent” means any chemical or biological material suitable for transdermal administration, including antiinfectives (p. 8-9) and Visser et al. teach that DMF is a drug that may be transdermally delivered to treat viral or microbial infections.

Regarding the functional language of claim 1, the invention as claimed is not structurally distinguishable from the combination of Ebert et al. and Visser et al. and it is therefore the examiner’s position that the ability of the permeability of the DMF is less than the permeability of human skin. Alternatively, since the permeability of DMF in the human skin is known (Visser et al., p. 27), it would have been within the purview of the skilled artisan to modify the thickness of the proximal and distal layers to adjust permeability, as is suggested by Ebert et al.

Regarding claim 5, Visser et al. teach that the patch may take the form of a disk and may be self-adhesive (p. 19, line 1 and 11).

Regarding claim 8, Visser et al. teach that colloidal silicone dioxide is impregnated with DMF (p. 26).

Regarding claim 11, Ebert et al. teach a method for making a transdermal drug delivery device comprising a proximal peelable film and an adhesive layer (claim 21).

**5. Claims 1, 4, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14, 1995) in view of**

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**Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) as applied to claims 1, 5, 8 and 11 and further in view of Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999).**

The combination of Ebert et al. and Vissar et al. teach each limitation of claims 1, 5 and 8. However, they fail to teach the proximal and distal layers the rate of permeability of DMF through the patch. Landauer et al. cure this deficiency.

Regarding claim 4, Landauer et al. teach that the tempo of drug administration is determined by the skin and thus the desorption of the drug through the membrane should be the same or very close to the absorption tempo of the skin (p. 14). Therefore, if the desorption of the drug through the membrane is the same as the absorption tempo of the skin, excess build-up of DMF on the skin of the patient is avoided.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Ebert et al. and Visser et al. with those of Landauer et al. to modify the desorption of the drug through the patch to be the same as the absorption tempo of the skin. One would have been motivated to do so because Visser et al. teach that DMF is a mild to moderate skin irritant (p. 9).

Regarding claim 7, Visser et al. teach that DMF is absorbed through the skin at 9.4 mg/cm<sup>2</sup>/hr (p. 27). Landauer et al. teach that the tempo of drug administration is determined by the skin and thus the desorption of the drug through the membrane should be the same or very close to the absorption tempo of the skin (p. 14). Therefore, Landauer et al. teach that the patch may have a permeability of about 9.4 mg/cm<sup>2</sup>/hr. MPEP 2144.05 states that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the

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art would have expected them to have the same properties” (quoting *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 774 (Fed. Cir. 1985)). In the instant case, about 9.4 mg/cm<sup>2</sup>/hr is so close to 9 mg/cm<sup>2</sup>/hr that the patch is expected to have the same permeability properties and reduction in buildup of DMF on the skin of the patient.

Regarding claim 9, Landauer et al. teach that indirect administration of DMF may be done by introducing a known amount of DMF with a syringe into the silicon dioxide adsorbent after the patch has been applied to the skin (p. 17).

**6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14, 1995), Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) and Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999) as applied to claims 1, 4-9 and 11 above, and further in view of Reed (US 5,827,530) (pub. Oct. 27, 1998).**



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The combination of Ebert et al., Visser et al. and Landauer et al. teach each aspect of claim 9. While they teach that DMF may be injected into the patch after the patch has been applied to the patient, they fail to teach that there is a self-reclosing nipple or port formation. Reed cures this deficiency.

Regarding claim 12, Reed teaches a fillable transdermal delivery device that utilizes injection ports for post assembly introduction of medicinally active agents (abstract). The fillable reservoir of the transdermal device is filled by means of loading a needle with the active agent and inserting the needle through the septum of the loading port (abstract).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Ebert et al., Visser et al. and Landauer et al. with those of Reed. to use an injection port for injecting DMF into the patch reservoir. One would have been motivated to do so because this allows the person injecting the DMF to inject the DMF into the reservoir and not into another part of the patch. Further, Reed provide a shield in the interior of the fillable reservoir to protect the diffusion membrane from damage in the event that the needle is inserted too far (abstract).

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

No claims are allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./

Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611